

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-44V

Filed: January 14, 2020

(Not to be published)

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LORI CARRE,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Findings of Fact; Onset;
Shoulder Injury Related to Vaccine
Administration (“SIRVA”).

*Isaiah Kalinowski, Maglio Christopher and Toale, PA, Washington DC, for Petitioner.
Emilie Williams, U.S. Department of Justice, Washington, DC, for Respondent.*

RULING ON ONSET¹

Oler, Special Master:

On January 8, 2018, Lori Carre (“Ms. Carre” or “Petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² (the “Vaccine Act” or “Program”). The petition alleges that the influenza (“flu”)

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** However, the parties may object to the Decision’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

vaccination Ms. Carre received on October 5, 2015 caused her to suffer from Shoulder Injury Related to Vaccine Administration (“SIRVA”). Pet. at 1.

During the pendency of this matter, Petitioner submitted one affidavit that she authored, along with affidavits prepared by her husband, and a work associate, as well as other documentary evidence.

I held a hearing on December 10, 2019 in Washington, DC, to determine the date of onset of Petitioner’s shoulder pain. Mr. Isaiah Kalinowski appeared on behalf of Petitioner and Ms. Emilie Williams appeared on behalf of Respondent. I heard testimony from Petitioner and her husband.

After carefully considering the testimony of the witnesses, the medical records, affidavits, and documentary evidence, I find that Petitioner’s left shoulder pain began the day of her vaccination.

I. Procedural History

On January 8, 2018, Petitioner filed a petition alleging that she suffered from SIRVA as a result of a flu vaccine administered on October 5, 2015. Pet., ECF No. 1. Petitioner filed medical records on January 22, 2018. Exs. 1, 2, 3, 4, 5, 6. On this same date, Petitioner filed email correspondence between Renee DeMarzio and David Wrzesniewski. Petitioner also filed her affidavit along with an affidavit from Renee DeMarzio. Exs. 8, 9. She filed additional medical records on April 12, 2018 and July 31, 2018. Exs. 12, 13.

On December 14, 2018, Respondent filed a Rule 4(c) Report. ECF No. 23. Respondent stated that Petitioner has not demonstrated that she suffered from a SIRVA Table claim, and further has not provided evidence that satisfies her burden of proof under *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). Resp’s Rept. at 8-10.

I held a status conference with the parties on February 14, 2019. See ECF No. 26. During the status conference, I informed the parties that I found the evidence submitted by Petitioner, in particular the affidavit and email correspondence from Ms. DeMarzio to be compelling. I asked Respondent’s counsel whether an onset hearing would assist in moving the case forward. I specifically informed counsel that “I hesitate [to conduct an onset hearing] if the outcome will not alter Respondent’s position.” ECF No. 26. Counsel for Respondent informed me that she would provide my initial assessment of the case to her client and inquire whether an onset determination would assist in resolving the case.

On March 18, 2019, the parties filed a joint status report. ECF No. 27. In this report, Respondent indicated that “he would find an onset determination valuable in encouraging possible settlement negotiations.” ECF No. 27.

On June 6, 2019, Petitioner filed additional medical records. Ex. 14. She also filed a supplemental affidavit from Renee DeMarzio. Ex. 15.

I conducted a fact hearing on December 10, 2019 in Washington, DC. The matter is now ripe for adjudication.

II. Petitioner's Medical Records

Petitioner was born in 1971. She was 44 years old on October 5, 2015, when she received the allegedly causal flu vaccination in her left deltoid at Giant Pharmacy. Ex. 1 at 2. Prior to her vaccination, Petitioner had a history of thyroid cancer. Ex. 5 at 2.

Petitioner went to PMA Medical Specialists on February 8, 2016 for thyroid problems. Ex. 5 at 11. There is no indication in the record that Petitioner mentioned shoulder pain during this visit.

Petitioner next sought medical treatment on June 17, 2016. She complained of pain in the left upper arm which began "8 months ago." Ex. 5 at 14. This record also indicated that the "pain started 11/2015 after a flu shot." *Id.* The notes from this visit state that several co-workers also have similar symptoms. *Id.* Petitioner was scheduled for an MRI. *Id.* at 15.

Petitioner had an MRI on July 7, 2016. Ex. 3 at 6. The impression is listed as:

Minor edema involving the left deltoid muscle. No overt disruption of fibers. This could be sequela of prior trauma. This could be related to minor strain or nonspecific myositis[.] Extremely subtle, minor muscular edema involving the brachioradialis muscle. Similar differential considerations[.] Mild degenerative change shoulder.

Id. at 6-7.

On July 20, 2016, Petitioner visited Dr. Louis Simonetti at PMA Medical Specialists for left shoulder pain. Ex. 5 at 16. These records indicate that her left shoulder pain began nine months ago after her flu shot, and that she has pain with movement of her left shoulder. *Id.* Dr. Simonetti assessed Petitioner with sprain of other part of left shoulder region "[a]cute-secondary to flu shot." *Id.* at 18.

On August 2, 2016, Petitioner visited Dr. John Pell at Rothman Institute. Ex. 6 at 9. The history of present illness section of the record states that Petitioner "has difficulty with her left arm in the area of her deltoid insertion. It started after she had a flu injection in this spot." *Id.* Dr. Pell assessed Petitioner with bursitis of the left shoulder and myopathy of the left arm secondary to flu injection. *Id.*

Petitioner attended her first physical therapy session at ATI Physical Therapy on August 11, 2016. Ex. 2 at 2. She attended a total of 10 visits before being discharged on September 6, 2016. *Id.*

On August 16, 2016, Petitioner followed up with Dr. Pell and indicated that her arm pain had not improved since beginning physical therapy. Ex. 6 at 7. She was assessed with bursitis of

the left shoulder and was told to follow up in four weeks. *Id.*

Petitioner underwent an MRI of her left shoulder on September 8, 2016. Ex. 6 at 14. The impression from this imaging is listed as “Supraspinatus tendinosis[;] SLAP tear with extension into posterior labrum[;] Possible synovitis at axillary pouch.” *Id.* at 15.

Petitioner followed up with Dr. Pell on September 13, 2016 complaining of persistent left shoulder pain. Ex. 6 at 4. Dr. Pell states in this record that

The internal derangement of her left shoulder is not caused by her flu shot, but may have been exacerbated by it. I think that most of her discomfort persistent from her flu shot may well be related to inflammation of the deltoid and the brachioradialis.

Id.

Petitioner visited Dr. Pell on April 24, 2018 for left shoulder pain. Ex. 13 at 2. The record indicates that “she had previously had a flu shot which caused her a great deal of shoulder pain and her pain has persisted since the time of her flu shot.” *Id.*

III. The Petition, Affidavits, and Documentary Evidence

The Petition filed in this matter states that Petitioner experienced a SIRVA following her October 5, 2015 flu vaccination. Petition at 1-3.

A. Affidavits

1. Affidavit of Ms. Lori Carre

In support of her Petition, Ms. Carre signed her affidavit on January 12, 2018. In it, she states that she received her flu vaccination on October 5, 2015 at the Giant Pharmacy in Audubon, Pennsylvania. Ex. 8 at 1. Petitioner states she felt pain “from the moment of injection.” *Id.* According to Ms. Carre, she did not think much of the pain at the time, because she knew vaccinations could be painful. *Id.*

Over the next few weeks, Petitioner’s pain did not dissipate. Ex. 8 at 1. At that time, she states that she discussed her continuing pain with Renee DeMarzio, her coworker and employer’s benefits coordinator. *Id.* at 2. According to Petitioner, Ms. DeMarzio also experienced similar pain after her vaccination. *Id.*

By December 2015, Petitioner, along with two of her coworkers, had all experienced shoulder pain after vaccination. Ex. 8 at 2. One of these coworkers went to the doctor and learned that the injection had likely been placed too high in the arm, but that there was no treatment that would address the pain. *Id.* According to Petitioner, when she learned that there was no way to help with the pain, she decided there was “not much reason for me to seek medical attention for my shoulder injury.” *Id.* Petitioner decided to rest her arm and wait for it to resolve on its own. *Id.*

Petitioner states that Ms. DeMarzio communicated with the manager of the Giant Pharmacy and let him know that there were four employees who experienced pain after receiving a flu vaccination. Ex. 8 at 3. The pharmacy manager recommended that Ms. DeMarzio contact David Wrzesniewski. *Id.* Mr. Wrzesniewski suggested that the four who experienced pain after flu vaccine should file a VAERS report. *Id.* Petitioner states that she filed her form in December 2015 or January 2016. *Id.*

In June of 2016, Petitioner spoke with Marion Fisher “a representative from Giant Pharmacy’s risk management firm.” Ex. 8 at 4. According to Petitioner, Ms. Fisher recommended that Petitioner have an MRI. *Id.* After that conversation, Petitioner began to visit medical professionals to treat her shoulder pain. *Id.*

Petitioner states that she still experiences pain from her shoulder injury. Ex. 8 at 4.

2. Affidavit of Ms. Renee DeMarzio

Ms. DeMarzio is the benefits coordinator at Globus Medical, where Petitioner is an employee. Ex. 9 at 1. Ms. DeMarzio set up the annual flu vaccinations for the company’s employees. *Id.* The majority of employees received their flu vaccines on one of two dates. *Id.* However, Petitioner was not available on either of the dates that Ms. DeMarzio had arranged, so Petitioner received a voucher that enabled her to go to Giant to receive her flu vaccine. *Id.* at 2.

A couple of weeks after both she and Petitioner received their flu shots, Petitioner told Ms. DeMarzio about her left arm pain that was so intense that it made Petitioner think she was having a heart attack. Ex. 9 at 2. Ms. DeMarzio states that three days after this conversation, she also felt this same type of pain that Petitioner had described. *Id.*

One day in December, another employee came to Ms. DeMarzio and mentioned persistent pain since the flu vaccine. Ex. 9 at 2. This employee went to the doctor, and the doctor told her it was probably a result of improper administration of the vaccine. *Id.* Ms. DeMarzio discussed this other employee with Petitioner, and they “all came to realize that [they] had all received [their] vaccinations from that pharmacist Lauren.” *Id.*

After making this realization, Ms. DeMarzio spoke with a manager of the Giant Pharmacy. Ex. 9 at 2. The manager asked her to contact David Wrzesniewski, who recommended they each file a VAERS report. *Id.* Each affected employee completed the VAERS form, and Ms. DeMarzio submitted the completed forms. *Id.* One day after submitting these forms, another employee came to Ms. DeMarzio complaining of persistent pain that began after his flu shot. *Id.*

3. Affidavit of Mr. Kevin Carre

Mr. Carre is Petitioner’s husband. Ex. 10 at 1. He recalls that Petitioner complained about pain associated with her flu shot “in the days and weeks immediately following...” *Id.* When the pain got worse over time, it became worrisome for them. *Id.*

According to Mr. Carre, Petitioner contacted a representative at Giant to discuss the matter. Ex. 10 at 1. Petitioner told Mr. Carre that some of her coworkers had also experienced similar pain after their flu shots. *Id.*

4. Supplemental Affidavit of Renee DeMarzio

Ms. DeMarzio completed her supplemental affidavit on June 6, 2019. In that document, she states that she remembers the initial conversation she had with Petitioner about shoulder pain. Ex. 15 at 1. They were walking down the hallway and Petitioner mentioned to her that “she thought she was having a heart attack the night before because she had such pain in her left arm.” *Id.* She does not recall the specific date of this conversation. *Id.* at 2. Further, Ms. DeMarzio does not recall whether Petitioner discussed when this pain began. *Id.*

Ms. DeMarzio states that there were four employees (her, Petitioner, and two others) who experienced shoulder pain after vaccination. Ex. 15 at 2.

B. Documentary Evidence

Petitioner filed email correspondence between Renee DeMarzio and David Wrzesniewski. Ex. 7. The email string began in December 2015 when Ms. DeMarzio emailed Mr. Wrzesniewski informing him that some employees were still experiencing pain after their flu shots. Ex. 7 at 4. Petitioner also filed the VAERS form she completed concerning her shoulder pain after her October 5, 2015 flu shot. Ex. 12.

C. Testimony at the Hearing

1. Testimony of Kevin Carre

Petitioner’s husband, Kevin Carre testified briefly at the hearing. He testified that after Petitioner received her flu shot in October of 2015, she complained of normal pain associated with vaccination. Tr. at 8. A couple of days after her vaccination, Petitioner began to describe increased pain, which included pain that radiated down her arm. *Id.* at 5.

As time went on, Petitioner’s pain increased. Tr. at 8. Her shoulder pain prevented her from engaging in daily activities without experiencing pain. *Id.* at 6. For example, Petitioner had problems getting dressed and had difficulty sleeping. *Id.*

2. Testimony of Petitioner

Petitioner testified that before her vaccination, she had never injured her shoulder. Tr. at 11-12. On October 5, 2015, Petitioner received her flu vaccination in her left shoulder at Giant Pharmacy. *Id.* at 13. The pharmacist injected her at the mid-point between her shoulder and her elbow. *Id.* at 14. Petitioner testified that she experienced pain associated with the shot the same day that she received it, but thought it was normal vaccination pain. *Id.* at 15, 16.

As time went on, Petitioner testified that she experienced a progression of symptoms. Tr. at 16. Within one week of vaccination, Petitioner was unable to sleep on her stomach without pain. *Id.* at 17. She had a hard time carrying things, and had difficulty reaching over her head. *Id.* at 18. Petitioner described her pain as constant but explained there were times when it increased in intensity. *Id.* at 19. One night, the pain in her arm woke her from sleep. The pain was so intense, Petitioner thought she might be having a heart attack. *Id.* at 20, 21. This incident took place in the beginning of November. *Id.* at 21.

Soon after this painful incident, Petitioner spoke with Renee DeMarzio, her coworker and her company's benefits coordinator. Tr. at 21-22. Petitioner told Ms. DeMarzio about experiencing such extreme arm pain that she thought she was having a heart attack. *Id.* Ms. DeMarzio told Petitioner that there were other coworkers who also still felt pain after their flu shots. *Id.* at 22. According to Petitioner, Ms. DeMarzio reached out to the pharmacy, who recommended individuals still experiencing pain from vaccination complete VAERS forms. *Id.* at 23-24. Petitioner testified that she completed her VAERS form either in late December or in January. *Id.* at 24, 25-26. To the best of her knowledge, she believes she completed the form in late December 2015. *Id.* at 24.

Petitioner attended a medical appointment in February 2016 with Dr. Ali. Tr. at 26. Dr. Ali is her endocrinologist. *Id.* Because of this, Petitioner did not mention her symptoms of shoulder pain at this appointment. *Id.*

Petitioner first learned that vaccines could cause the type of pain that she experienced when she did an internet search soon after her first MRI, in July 2016. Tr. at 33-34. She did not know of SIRVA or the Vaccine Program when she received her vaccination. *Id.* at 34.

IV. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing her claim by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). A petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

In order to make a determination concerning factual issues, such as the timing of onset of petitioner’s alleged injury, the special master should first look to the medical records. “Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium.” *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Lowrie v. Sec’y of Health & Human Servs.*, No. 03-1585V, 2006 WL 3734216, at *8 (Fed. Cl. Spec. Mstr. Nov. 29, 2006). Medical records created contemporaneously with the events they describe are presumed to be accurate and complete. *Doe/70 v. Sec’y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010).

Contemporaneous medical records generally merit greater evidentiary weight than oral testimony; this is particularly true where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also* *Murphy v. Sec’y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d*, 968 F.2d 1226 (Fed. Cir. 1992)(citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) (“It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight”)). “Written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.” *Reusser v. Sec’y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993).

However, there are situations in which compelling oral testimony may be more persuasive than written records--for instance in cases where records are found to be incomplete or inaccurate. *Campbell*, 69 Fed. Cl. at 779 (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475, at *19 (“Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733).

When witness testimony is used to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez v. Sec’y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825 (Fed. Cl. Spec. Mstr. Apr. 10, 2013)(citing *Blutstein v. Sec’y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). A special master making a determination whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at a hearing must have evidence suggesting the decision was a rational determination. *Burns by Burns v. Sec’y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993).

V. Findings of Fact

The issue to be addressed is when Petitioner’s symptoms of left shoulder pain began. Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a preponderance of the evidence. § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be “more probable than its nonexistence.” *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring). In light of the witness testimony, medical records, affidavits, and other documentary evidence presented in this case, and after my careful examination of the record as a whole, I find there is preponderant evidence that the onset of Petitioner’s symptoms of left shoulder pain began on October 5, 2015, the day of vaccination.

In her affidavit and during her testimony at the hearing, Petitioner attests that she experienced pain the same day that she received her flu vaccination. I find her testimony on this point to be credible, and further find this testimony is corroborated by her medical records, and by the affidavits and email correspondence of Ms. DeMarzio.

Petitioner did not seek medical attention for her shoulder pain until June 17, 2016, more than eight months after her vaccination. However, when Petitioner did seek treatment for her pain, she consistently attributed her left shoulder pain to her flu shot.³ *See* Ex. 5 at 14; Ex. 5 at 6; Ex. 6 at 9; Ex. 13 at 2. Accordingly, Petitioner's medical records support a finding that Petitioner experienced pain close-in-time to her flu vaccination.

The affidavits of Ms. DeMarzio and the email correspondence between Ms. DeMarzio and Mr. Wrzesniewski are especially compelling. Ms. DeMarzio confirms that she spoke with Petitioner about Petitioner's pain several weeks after vaccination. Ms. DeMarzio indicates that after she experienced similar symptoms, and when another employee came to her complaining of shoulder pain after the flu shot, she reached out to Giant Pharmacy and then sent an email to David Wrzesniewski. Her initial email to Mr. Wrzesniewski is dated December 17, 2015 and indicates that she has received "complaints from some employees about their flu shot area still hurting." *Id.* at 3-4. This email corroborates Petitioner's claims articulated in her affidavit and in her testimony at the hearing. Specifically, Petitioner has consistently maintained that she felt immediate pain after her vaccination.

VI. Conclusion

I find that the affidavits submitted by and on behalf of Petitioner, the testimony, the medical records, and the other documentary evidence work in concert to provide preponderant evidence that Petitioner's left shoulder pain began on October 5, 2015

The following is therefore ORDERED:

By no later than **Monday, March 16, 2020**, Petitioner and Respondent shall file a joint status report updating me on their proposed next steps in the case based on the facts articulated in this ruling.

IT IS SO ORDERED.

s/ Katherine E. Oler

Katherine E. Oler

Special Master

³ These records generally indicate that pain began "after a flu shot" and do not specifically discuss whether the pain began within 48 hours of injection. I find there is preponderant evidence that Petitioner's pain began within 48 hours of her flu shot for the reasons articulated in this decision.